

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

THIS PAGE BLANK (USPTO)

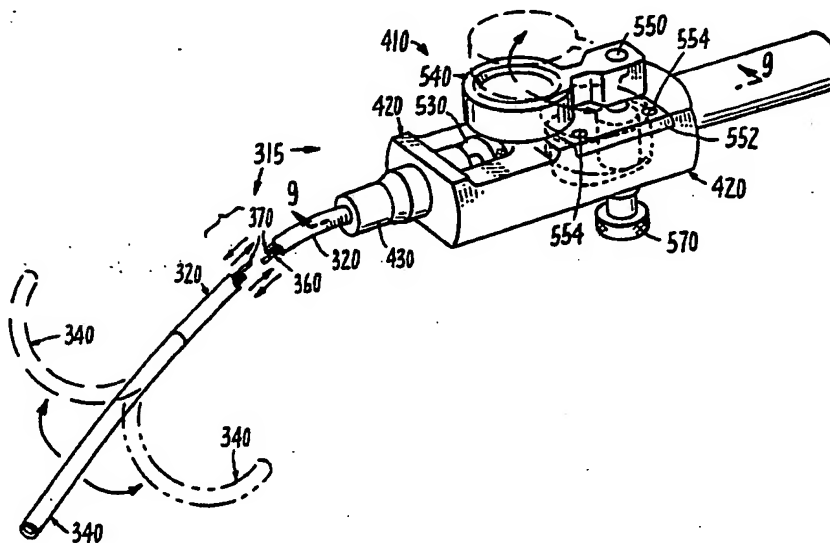


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 37/00	A1	(11) International Publication Number: WO 91/11213 (43) International Publication Date: 8 August 1991 (08.08.91)
(21) International Application Number: PCT/US91/00662 (22) International Filing Date: 31 January 1991 (31.01.91) (30) Priority data: 473,667 2 February 1990 (02.02.90) US (71) Applicant: EP TECHNOLOGIES, INC. [US/US]; 897 Independence Avenue, Suite 1-D, Mountain View, CA 94043 (US). (72) Inventors: LUNDQUIST, Ingemar ; 17 Mile Drive at the Dunes Road, Pebble Beach, CA 93953 (US). THOMPSON, Russell, Blake ; 3266 Sweetwater Drive, San Leandro, CA 94578 (US).		(74) Agents: RAINEY, Matthew, C. et al. ; Irell & Manella, 545 Middlefield Road, Suite 200, Menlo Park, CA 94025 (US). (81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: CATHETER STEERING MECHANISM**(57) Abstract**

A steering mechanism (315) including a steering shaft (320) coupled to a controller (410) which includes a handle (540) and apparatus for manipulating the distal end (340) of the steering shaft. The steering shaft includes a flexible coiled spring (170) having a lead spring (350) fixed in position with respect to a distal end thereof in the distal end of the steering shaft. One or more steering wires (360, 370) is affixed at the distal ends thereof to the lead spring. The steering wires extend through the steering shaft to the controller, and the steering apparatus of the controller is used to place tension on one or both of the steering wires. The attachment of the distal ends of the steering wires to the lead spring may be opposite one another or may be offset for providing greater maneuverability. Tension may be placed on the steering wires by wedges (650, 660) mounted transversely to the controller housing, or by rotation of a shaft (450) mounted transversely to the controller housing, the steering wires being attached to the shaft such that rotation in one direction tensions one steering wire, and rotation in the other direction tensions the other steering wire. Two independently rotatable shafts (1560, 1590) may be used to separately control the two steering wires. The steering shaft is adapted for insertion into a lumen (45) of a catheter (40) for use in guiding the distal end of the catheter to a treatment site within a patient. The steering mechanism may also be used in conjunction with tools or apparatus which must reach into difficult locations, such as engines or other machines.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

5

CATHETER STEERING MECHANISMBackground of the Invention

This invention relates to a steering mechanism for use with medical catheters or other devices which need to be positioned in difficult locations.

In many medical procedures, it is necessary to position a catheter at a location within a patient's body. A typical emplacement for the distal end of a catheter might be within a ventricle of the heart, by way of the femoral vein. In so passing a catheter through the femoral vein, it is necessary to avoid obstructions, vessel junctions and the like, and to make sharp turns to position the distal end of the catheter within the ventricle. Other medical procedures involve similar difficulties in placing a catheter.

In conventional catheters used today, the tip of the catheter may be bent, or may include a stylet which is bent, such that a semipermanent curve is given to the distal end of the catheter so that a physician may guide the distal end thereof towards the treatment location. A disadvantage with this type of apparatus is that the curvature of the bend is not adjustable while the catheter is in the body, and any change in the curvature requires the physician to remove the catheter and reshape the distal end.

There is a need for a steering mechanism for catheters and other devices wherein the distal end of the device can be manipulated at will from a location outside the patient's body or outside the apparatus in which the device is placed. Accordingly, it is an object of the present invention to provide such a steering mechanism,

and in particular to provide such a mechanism which provides a wide range of steerability.

It is another object of the invention to provide such a mechanism which may be completely manipulated with one hand.

It is a further object of the invention to provide such a steering mechanism wherein the distal end of the mechanism may be bent into varying shapes for placement in different positions while the mechanism is in use.

Other objects and advantages will more fully appear in the course of the following discussion.

Summary of the Invention

The steering mechanism of the invention includes a flexible steering shaft attached to a controller. The controller includes a handle with a central bore in which one or more steering wires are carried. The steering shaft includes a flexible coil, at the distal end of which a ferrule is positioned. Mounted on the ferrule is a lead spring, which extends to the distal tip of the steering shaft. The steering wire has a distal end which is welded or otherwise affixed to the distal end of the lead spring. Tension may be placed on the steering wire by manipulating the controller, thus turning the distal end of the steering shaft.

In use, the steering shaft is inserted into a lumen of a catheter, and the controller is manipulated to turn the distal end of the catheter.

In a preferred embodiment, two steering wires are provided, one attached to each side of the lead spring at the distal end of the steering shaft. The two steering wires may be attached at points directly opposite one another on the lead spring, or they may be offset to provide for different configurations of the distal end of the steering shaft when tension is placed on one, the other, or both steering wires.

In one embodiment, the controller includes a wedge mounted transversely to the handle of the controller, the wedge receiving the steering wire and being tapered such that pushing the wedge in one direction places tension on the steering wire, and pushing it in the other direction releases tension from the steering wire. In a two steering wire embodiment, two wedges are provided, positioned such that their tapered portions run opposite to one another, for providing two-way steering of the distal end of the steering shaft.

In another embodiment of the invention, two steering wires may be attached to a rotatable shaft which is mounted on an axis transverse to a longitudinal axis of the handle of the controller. A central knob is attached to the shaft, such that turning it one way places tension on one of the steering wires and turning it the other way places tension on the other steering wire.

In an alternative embodiment of the invention, the two steering wires are attached to two separate rotatable shafts mounted on the controller, and the shafts may be independently rotated for independent control of the steering wires.

In a preferred embodiment of the invention, regions of the steering shaft at the distal end thereof are enlarged in diameter to allow for greater bending of the distal end at those regions.

Variations on these and other embodiments are described below.

Brief Description of the Drawings

Figure 1 shows a steering mechanism of the invention.

Figure 2 is an enlarged perspective view of a portion of the mechanism of Figure 1.

Figure 3 is an enlarged perspective view similar to Figure 2, showing a different position for the mechanism.

Figure 4 is a sectional view of the mechanism of Figure 1 in yet another position.

Figure 5 is a sectional view taken along line 5-5 of Figure 4.

Figure 6 is a sectional view taken along line 6-6 of Figure 1.

Figure 7 is a perspective view of an alternative embodiment of the invention.

Figure 8 is a sectional view of a distal end of the embodiment of Figure 7.

Figure 9 is a sectional view taken along line 9-9 of Figure 7.

Figure 10 is a sectional view taken along line 10-10 of Figure 9.

Figure 11 is a perspective view of another embodiment of the invention.

Figure 12 is a sectional view taken along line 12-12 of Figure 11.

Figure 13 is a sectional view taken along line 13-13 of Figure 12.

Figure 14 is a perspective view of yet another embodiment of the invention.

Figure 15 is a sectional view taken along line 15-15 of Figure 14.

Figure 16 is a perspective view, partially cut away, of another embodiment of the invention.

Figure 17A is a top view, partly cut away, of the embodiment of Figure 16.

Figure 17B is a sectional view taken along line 17B-17B of Figure 17A.

Figure 18 is a perspective view of another embodiment of the invention.

Figure 19 is a top view of the embodiment of Figure 18.

Figure 20 is a perspective view of another embodiment of the invention.

Figure 21 is a sectional view of the distal end of the embodiment of Figure 20.

5 Figure 22 is a sectional view like that of Figure 21, in a straightened position.

Figure 23 is a top view, partially cut away, of the embodiment of Figure 20.

10 Figure 24 is a sectional view taken along line 24-24 of Figure 23.

Figure 25 is a sectional view of an alternative embodiment to the distal end of a steering mechanism of the invention.

15 Figure 26 is a sectional view taken along line 26-26 of Figure 25.

Figure 27 is a sectional view taken along line 27-27 of Figure 25.

20 Figure 28 is a sectional view taken along line 28-28 of Figure 25.

Figure 29 is an exploded view showing detail of a portion of the invention.

Figure 30 is a sectional view of a portion of the steering mechanism of the invention.

25 Figure 31 is a sectional view taken along line 31-31 of Figure 30.

Figure 32 is a sectional view taken along line 32-32 of Figure 30.

Figures 33 and 34 are sectional views of an alternative embodiment of the invention.

30 Figure 35 shows the embodiment of Figure 1 in use with a conventional medical catheter.

Figure 36 shows an alternative embodiment to the distal tip of the invention.

35 Description of the Preferred Embodiments

Figure 1 shows a steering mechanism 10 including a controller 15 with a handle 20. A flexible

steering shaft 30 is attached at its proximal end 40 to the controller 15. The shaft 30 is formed from any conventional material which is flexible, slightly elastic to tolerate bending without permanent deformation, and biocompatible for applications in the medical field. Preferably, the shaft 30 is formed from TEFLON (tetrafluoroethylene) for minimizing friction with other elements of the apparatus.

The mechanism 10 may be used to steer and position many different types of apparatus, and the embodiment shown in Figure 1 is adapted for use with medical catheters. As shown in Figure 35, the steering shaft 30 is positioned within a lumen 45 of a catheter 40, the distal tip 48 of the catheter 40 is maneuvered to a desired position within a patient's body, and the steering mechanism may then be removed so that the lumen 45 may then be used by the physician for introduction of treatment drugs or the like to the patient. The catheter may include also conventional ports for this purpose, such as ports 41 and 42 shown in Figure 35 which communicate with one or more additional lumens (not separately shown) within the catheter 40.

The catheter 40 is any standard catheter, such as an angioplasty catheter (for laser angioplasty, balloon angioplasty, or other treatments), a catheter with pacing and/or sensing probes, or indeed any flexible or steerable device which one may wish to introduce into a place which is difficult to reach. Such devices need not be confined to the medical field. Other important applications include the introduction of tools (for inspection, adjustment, or repair) into engines or other machines, and the manipulation of objects in any type of conduit. For inspection purposes, fiber optics may be carried by the catheter 40 or other device. In machine repair and adjustment applications, any convention tool may be attached to the distal end of the steering shaft 30, such as drill bits, clamps, wrenches, grinders, and

so n, and th se tools may be remotely operated from the
controll r 15. Thus, alth ugh th present emb diments of
th inventi n are described primarily in terms of use
with a catheter, the invention has many other

5 applications.

In the course of the following discussion, it
will be understood that the manipulation, steering or
positioning of the shaft 30 (or other shafts of the
alternative embodiments) results in concomitant manipula-
10 tion, steering or positioning of the catheter or other
device with which the steering mechanism is used. Any of
the following embodiments may be used with the catheter
40 shown in Figure 35 or other steerable device.

The steering mechanism 10 includes a first
15 sleeve 50, as shown in Figures 1 and 6, adjacent which is
positioned a second sleeve 60. The sleeve 50 includes a
stop 70 at its interior, as shown in Figure 6, against
which the second sleeve 60 abuts. The second sleeve 60
has an outer diameter closely matching the inner diameter
20 of the first sleeve 50.

A third sleeve 80 is positioned within a
forward portion of the second sleeve 60, and has an outer
diameter closely matching the inner diameter of the
forward portion. The third sleeve 80 has an inner
25 diameter closely matching the outer diameter of the
steering shaft 30. The sleeves 50, 60 and 80 are firmly
fixed so that they do not move relative to one another.
As shown in Figure 6, the steering shaft 30 is seated
against a shoulder 85 of the sleeve 60. The sleeve 60
30 acts as a cable or wire retainer for the steering wire
120.

Alternatively, for ease of manufacture the
sleeves 50, 60 and 80 may be of a unitary design.

As shown in Figure 35, the catheter 40 includes
35 a proximal end 43 which fits tightly against the sleeves
60 and 80 when the steering shaft 30 is inserted all the
way into the lumen 45 and is seated against shoulder 85

shown in Figure 6. The end 43 may be attached to the controller 15 by means of a standard Luer lock 44.

The handle 20 shown in Figures 1 and 6 is generally cylindrical in shape and includes a forward section 90 (shown in dotted fashion in Figure 1), a middle section 100, and a rear section 110. The forward section 90 has an outer diameter closely matching the inner diameter of the first sleeve 50, and is positioned within the sleeve 50 in a slidable fashion. The middle section 100 has a reduced outer diameter, and the rear section 110 has an outer diameter which is chosen for a comfortable grasp by the hand of the operator.

The sleeves 50, 60, and 80 and the three sections of the handle 20 all include central bores which are coaxially aligned for receiving a steering wire 120, as shown in Figure 6. One end of the wire 120 is clamped in position relative to the handle 20 by means of a screw 130, shown in Figure 1, which is threaded into a bore 140, shown in Figure 6.

The steering wire 120 includes a distal end 150 which is flattened in the preferred embodiment such that it has a rectangular cross section, and extends into a distal end 160 of the shaft 30. A coiled spring or sleeve 170 defines a central lumen 180 within the steering shaft 30, in which lumen the steering wire 120 is positioned. A ferrule 190 is positioned within the shaft 30 immediately distal of, and abutting, the coiled spring 170. The ferrule 190 includes a central lumen 200, and two slots 210 and 220 (as shown in Figure 29) which are disposed radially opposite one another, and together form a single transverse slot.

A flat, flexible lead spring 230 is positioned within the slots 210 and 220. The lead spring 230 includes a tongue 240 on its proximal end, which has a width closely matching the inner diameter of the ferrule 190. The lead spring 230 also includes a broader portion 250 with an outer diameter closely matching the outer

diameter of the ferrule 190. Thus, when the lead spring 230 is positioned as shown in Figures 2 and 3, the tongue 240 (Figure 29) is within the ferrule 190, and the proximal end of the broader portion 250 abuts the bottom ends of the slots 210 and 220. With the ferrule 190 and lead spring 230 in the position shown in Figure 1, the distal end 150 of the steering wire 120 is welded or otherwise attached to the lead spring 230, such as at weld 260.

10 As shown in Figure 5, the ferrule 190 and the shaft 30 have inner diameters which are substantially greater than the combined thickness 265 of the distal end 150 of the steering wire 120 and the lead spring 230.

15 In an alternative embodiment, shown in Figure 36, the ferrule 190 may be omitted, in which case the lead spring 230 is inserted into the coiled spring 170 in much the same fashion as into the ferrule 190, with the same dimensions applying to this embodiment. The lead spring 230 may be attached to the coiled spring 170 by
20 adhesive, solder, welds, or the like.

Referring now to Figures 1 and 6, the middle section 100 of the handle 20 includes a transverse slot therethrough, into which a control wedge 270 is positioned. The wedge 270 includes a larger end 280 tapering towards a smaller end 290. The wedge 270 also includes a slot 300 extending most of its length, as shown in Figures 1 and 6. The wedge 270 is positioned such that the wire 120 passes through the slot 300, as shown in Figure 6, in which position the slot 300 is
25 generally parallel to the longitudinal axis of the handle 20, and also is parallel to the proximal end of the wire 120. The ends 280 and 290, which form the ends of the slot 300, prevent the wedge 270 from accidental removal.

30 When the wedge 270 is in the upper position shown in Figures 1 and 6, the distal end 160 of the shaft 30 has the configuration shown in Figure 2. However, when the wedge 270 is pushed downward to the position

shown in dotted fashion in Figures 1 and 6, this forces the first sleeve 50 forwardly relative to the handle 20, by increasing the distance therebetween. Alternatively speaking, the handle 20 is forced rearwardly relative to the sleeve 50, into the position shown in dotted fashion (at the extreme right end) in Figures 1 and 6. The proximal end of the wire 120, being affixed by the screw 130, is similarly moved towards the right from the point of view of Figure 6, to the position shown in dotted fashion.

The wire 120 is thus pulled toward the right from the point of view of Figures 1-4 and 6, and thereby pulls the lead spring 230 at the weld 260, as shown in Figure 3. This bends the lead spring 230 in the direction of the distal end 150 of the wire 120, thus bending the distal end 160 of the shaft 30, as shown in Figures 2 through 4.

It will be appreciated that, because of the relatively large inner diameters of the ferrule 190 and the shaft 30, lateral torque or leverage may be exerted by the distal end 150 on the lead spring 230, in order to effect bending of the distal end 160 of the shaft 30. Thus, by providing enough radial play to the distal end 150 of the wire 120 and the lead spring 230, sufficient torque for steering the distal end 160 may be assured. The amount of radial play may be determined empirically for a given application, but in most cases a minimum inner diameter of the lead spring 230 and the shaft 30 of approximately two to three times the combined thickness 165 shown in Figure 5 will be sufficient to provide the necessary torque.

The materials for the wedge 270, the handle 20 and the sleeve 50 are chosen to provide sufficient friction, such that the wedge 270 maintains its position when it is located by the operator, so that the distal end 160 can be fixed in a variety of positions simply by repositioning the wedge 270. The wire 120 may

be tightened by loosening the screw 130, pulling the wire 120 tight, and then retightening the screw 130, which results in a change in the frictional fit of the wedge 270. Access to the proximal end of the wire 120 may be
5 had through an opening 310 in the rear section of the handle 130.

In the preferred embodiment, the lead spring 230 is affixed to the ferrule 190, and the ferrule 190 is in turn affixed to the coiled spring 170. This may be
10 done by adhesive, welds or the like, and is especially useful in conjunction with a catheter which is to be emplaced permanently or for a long period of time within a patient. The ferrule may alternatively simply be
15 abutted against the coiled spring 170, in which case the distal end 160 of the steering shaft is preferably formed from a heat shrink or other tightly fitting material to maintain the ferrule firmly in place.

In use, a physician will insert the catheter 40 into a patient, such as into the femoral vein, and will
20 insert the shaft 30 into the lumen 45. By manipulating the distal end 160 as necessary and pushing on the handle 20, the physician can negotiate a path to the treatment site, such as the heart. The physician may, by operating the control wedge 270, steer past any junction, turn or
25 obstacle which may be presented to the catheter simply by adjusting the control wedge such that the distal end 160 of the shaft 30, and hence also the distal end 48 of the catheter 40, takes on the necessary shape. Once a given obstacle or turn is negotiated by the end 160, it can
30 then again be straightened out by operation of the wedge 270, or may be changed to a different shape as necessary. If, for instance, the physician encounters a turn of the vein towards the right, the wedge 270 is pushed downward as shown in Figure 1, such that the distal end 160 takes
35 on the position shown in dotted fashion. If the vein then takes a turn to the left, the physician straightens out the distal end 160, rotates the handle 20 such that

the distal end 160 rotates the necessary amount (such as 180°), and then again operates the wedge 270 to manipulate the distal end 160 around the left turn. In this way, complete control over steering and emplacement
5 of the catheter 40 is achieved.

Figures 7-10 show an alternative embodiment, wherein left and right turns may be negotiated without rotation of the apparatus. The steering mechanism 315 shown in Figure 7 includes a flexible steering shaft 320
10 having a proximal end 330 and a distal end 340 and may be identical to the shaft 30 shown in Figure 1. As shown in Figure 8, carried within the distal end 340 are a lead spring 350 and two steering wires 360 and 370. The steering wires 360 and 370 are preferably rounded towards
15 their proximal ends, and flattened towards their distal ends, as with the steering wire 120 shown in Figure 1. The steering wires 360 and 370 are attached to the distal end of the lead string 350 by solder, adhesive, spot welds or the like, such as at welds 380 and 390. For
20 minimizing friction, the steering wires 360 and 370 (and the steering wires of any of the embodiments described herein) are preferably coated with TEFLON.

The lead spring 350, which may be identical to the lead spring 230 shown in Figure 2, is seated in a
25 ferrule 400, which is shown in Figure 8 and may be identical to the ferrule 190 shown in Figure 2. Thus, the configuration of the distal end 340 of the shaft 320 shown in Figure 8 is essentially identical to the distal end 160 of the shaft 30 shown in Figure 2, except that an
30 additional steering wire is attached to the lead spring 350. The mechanism 315 may be used in the same applications as the mechanism 10.

Figures 25-28 show further detail of the distal tip of a steering shaft of the embodiment of Figures
35 7-10, with Figures 26, 27 and 28 showing cross-sectional views at the regions indicated in Figure 25 along the length of the shaft 320. The numerals appearing in

Figures 25-28 are the same as those in Figures 7 and 8, but the details of these figures may be employed in any of the other embodiments described herein which utilize two steering wires.

5 In Figures 25-28, the shaft 320 is shown as used in conjunction with the catheter 40 shown in Figure 35. Preferably, the catheter 40 includes a standard braided or other torquable material, and the shaft 320 is adhered to the interior of the catheter 40 by adhesive
10 means such as glue 405 shown in Figures 25 and 27. With this configuration, torque on the proximal end of the catheter 40 will be transmitted to its distal end, and via the glue 405 will be transmitted to the shaft 320, thus allowing for turning of the distal end 340.
15 Alternatively, and especially in embodiments wherein no catheter is used, the shaft 320 may be made of a torquable material.

 Distal end 340 of the shaft 320 receives the lead spring 350 and the steering wires 360 and 370, as
20 shown in Figure 25. The rounded or circular proximal ends of the steering wires 360 and 370 are positioned within a coiled sleeve 375, as shown in Figure 28. The coiled sleeve 375 may be a conventional metal coil such as those used in medical catheters to provide
25 longitudinal stiffness but lateral flexibility. The steering wires 360 and 370 are flattened into a rectangular shape in the region near the lead spring 350.

 In the preferred embodiment, the steering wires 360 and 370 are attached at several places to the lead
30 spring 350, such as at the three spot welds 380 and the three spot welds 390, respectively, shown in Figure 25. The distal end 340 may be a heat-shrink material which, once the elements of the steering mechanism are assembled, is heated to reduce its diameter relative to
35 the main body of the shaft 320, thus tapering the tip in the region of the spot welds 380 and 390, as shown in Figure 25. When spot welds are used to attach the

steering wires to the lead spring, the use of heat-shrink is particularly advantageous in applying pressure to the welded region to prevent separation. When solder is used, this is not as important a consideration.

5 Figures 30-32 show an alternative embodiment of the distal end of the invention, wherein the proximal portions of the steering wires 360 and 370 are of non-circular cross section, such as the rectangular cross section shown in this embodiment. The steering wires 360
10 and 370 may be further flattened, as shown in Figure 31, in the region of the lead spring 350, thus providing greater clearance between the combined thickness 385 of the steering wires 360 and 370 and the lead spring 350, on the one hand, and the inner diameters of the ferrule
15 400 and the shaft 320, on the other hand. As discussed above relative to Figures 1-5 (and as shown in Figure 5), this clearance allows greater torque to be placed upon the distal tip of the steering shaft when the physician turns the distal tip by placing tension on the steering
20 wires.

Referring again to Figures 7-10, it will be seen that the configuration shown in Figures 25-28 (or 30-32) allows either left or right turns to be effected by pulling on the wire 360 or the wire 370, as shown in
25 dotted fashion for the distal end 340 in Figure 7. Figure 8 shows the configuration of the distal end 340 of the shaft 320 for a right turn, wherein rearward tension is placed on the steering wire 370 (represented by the right-facing arrow), and a forward force is simultane-
30 ously applied to the steering wire 360 (as represented by the left-facing arrow). The forward force to the wire 360 occurs both because of the push given to the wire 360 by the clockwise rotation of the spindle 450 (which is described in greater detail below), and because of the
35 pull exerted by the wire 370 via the welds 390, the lead spring 350, and the welds 380. When the spindle 450 is rotated counterclockwise, force is placed on the steering

wires 360 and 370 in directions opposit to the arrows shown in Figure 8, thus bending the distal end 340 to the left, as sh wn in d tt d fashion.

5 In order to provide such tension to the steering wires, a controller 410 is provided, as shown in Figures 7, 9 and 10. The controller 410 includes a housing 420 which receives the proximal end 330 of the shaft 320. Attached to the housing 420 is a coupling 430 which has a central bore 440 (shown in dotted fashion in
10 Figure 9) which is substantially coaxial with the lumen of the shaft 320.

The guide wires 360 and 370 pass through the bore 440, and are attached as shown in Figures 9 and 10 to a spindle 450. The preferred means of attachment is
15 by insertion through a bore 460 in the spindle 450, and the proximal tips 470 and 480 of the steering wires 360 and 370, respectively, are bent to prevent retraction through the bore 460. The wires are chosen to be stiff enough that they will retain the bent shape at their
20 proximal tips, and will not retract from the bore 460. Optionally, a taper pin 485 may also be used, being driven between the ends 470 and 480 into a frictional fit in a flared portion 465 of the bore 460, thus preventing the proximal tips 470 and 480 from accidental withdrawal.

25 The housing 420 includes a central passage 490, through which the steering wires 360 and 370 pass, and may include a threaded portion 500 in which an adjustable, threaded tension adjusting screw or bolt 510 is positioned. The tension bolt 510 includes a central
30 bore 520, as shown in Figure 10, and a knurled knob 530 for adjustment by hand. As shown in Figure 7, the knob 530 may be accessed by the operator of the controller 410 at any time, without disassembling the steering mechanism. The knob 530 is turned to adjust tension on
35 the steering wires 360 and 370, and to adjust the amount of play in the lead spring 350, as described in greater detail below.

The spindle 450 is mounted on an axis which is preferably transverse to a longitudinal axis of the housing 420, and is rotatable by means of a steering handle 540, which is connected to the spindle 450 by a shaft 550. The spindle 450 and associated steering apparatus are affixed to the housing by means of a plate 552 which is mounted to the housing 420 by means of screws or bolts 554.

The shaft 550 includes a threaded bottom end 560, onto which a tightening knob 570 is threaded. A washer 580 is preferably positioned between the knob 570 and the housing 420, and a resilient O-ring 590 is positioned adjacent the washer 580. Between the O-ring 590 and the knob 570 is positioned another washer 600.

The washers 580 and 600 and the O-ring 590 are all coaxial with and surrounding the threaded portion 560 of the shaft 550. Thus, when the knob 570 is rotated such that it is tightened (i.e., moved closer to the housing 420), the increased friction between the knob 570, the washers 580 and 600, the O-ring 590 and the housing 420 inhibits the shaft 550 from turning, thereby maintaining the handle 540 in any position set by the operator of the steering mechanism. The resiliency of the O-ring 590 allows the operator to adjust the friction by means of the knob 570 such that the handle 540 may be relatively easily rotated by pushing with the fingers, and yet such that the distal end 340 will not spring back to the straightened shape shown in Figure 7 (which would cause the handle 542 spring back to the central position shown in Figure 7) when the operator releases the handle 540. Alternatively, the knob 570 may be loosened such that whenever the operator manipulates the handle 540, and then releases the handle, the distal end 340 is allowed to straighten out--which it will do because of the tension of one or the other of the steering wires, such as the tension due to the steering wire 360 in the position shown in Figure 8.

In order to increase the tension in the steering wires 360 and 370 and decrease the rotational play in the handle 540, the knob 530 is rotated such that it moves to the left from the point of view of Figure 10 (which will be a counterclockwise rotation for right-hand threads), thereby exerting force on the proximal end 330 of the coiled sleeve 375 (the force being towards the left in Figure 10). The sleeve 330 is longitudinally relatively rigid, and thus the force on its proximal end is transmitted to its distal end, where it is exerted in turn on the ferrule 400, and thence onto the lead spring 350. The force on the lead spring 350 is transmitted to the steering wires 360 and 370 via the welds 380 and 390. Thus, any longitudinal play in the system is reduced or eliminated by the counterclockwise rotation of the tension bolt 510, which results in greater responsiveness in the rotational control of the lead spring 350 by means of the steering handle 540.

Conversely, tension on the steering wires is reduced, and greater play is given to the steering function, by rotating the knob 530 such that it moves towards the right from the point of view of Figure 10.

The embodiment of Figures 7-10, therefore, allows the operator of the steering mechanism to manipulate the catheter into whatever position desired, accommodating both left and right turns through the passages encountered in the body. At most, the distal end 340 of the shaft 320 will need to be rotated 90° to accommodate all possible twists and turns that might be encountered in the body. The controller 410 may be manipulated entirely with one hand, including both operating the handle 540 to position the distal end 340 into the right and left turn configurations shown in dotted fashion in Figure 7, and also including axial rotations of the distal end 340 should those become necessary.

Figures 11-13 show an alternative embodiment of the invention comprising a steering mechanism 635 which incorporates two steering wires 610 and 620 which extend through a flexible steering shaft 630. The portion of the mechanism extending to the left from the point of view of Figure 11 may be identical to the embodiment shown in Figures 7 and 8. The steering mechanism 635 of Figures 11-13 includes a controller 640 which constitutes an alternative to the controller 410 shown in Figures 7, 9 and 10.

The controller 640 includes a left control wedge 650 and a right control wedge 660 mounted in a housing 670. The housing 670 includes an opening 680 in which the control wedges 650 and 660 are positioned as shown in Figures 11 and 12, with control wedge 650 being tapered upwardly, and control wedge 660 being tapered downwardly. The wedges 650 and 660 may be identical, except that they are carried in opposite directions in the housing 670.

Control wedge 650 includes a slot 690, and control wedge 660 includes a slot 700. These slots terminate at the upper and lower ends of the control wedges, as shown in Figure 11.

The housing 670 includes a cavity 710 in which a left control block 720 and a right control block 730 are positioned, such that they may slide to the left and right from the point of view of Figures 11-13 (as shown by the double arrows in Figure 13). The left control block 720 includes a bore 740, and the right control block 730 includes a bore 750, into which the extreme proximal ends of the steering wires 610 and 620 extend, as shown in Figure 13. Screws 760 and 770 are provided, as shown in Figures 12 and 13, and are threaded into the control blocks 720 and 730 for clamping down the proximal ends of the steering wires 610 and 620.

As shown in Figures 11-13, the steering wires 610 and 620 extend from the steering shaft 630 through a

wire retainer 775, and through a bore 780 in the distal end of the housing 670, through the slots 690 and 700, and thence into the bores 740 and 750, where they are held in place by the screws 760 and 770. Thus, if left control block 720 is forced to the right from the point of view of Figure 13, then tension is placed on steering wire 610, thereby turning the distal tip of the steering shaft 630 (and also the distal tip of the catheter in which the shaft is positioned) to the left (as shown in dotted fashion in Figure 7). Likewise, if right control block 730 is forced to the right, tension is placed on the steering wire 620, forcing the distal tip of the steering shaft 630 (and the distal tip of the catheter) to the right. Again, only one hand is needed to operate the controller 640, and at most a 90° turn of the distal tip of the steering shaft 630 will be required to negotiate all twists and turns within the passages in the body of a patient. As will be discussed in further detail below, the controller 640 of Figures 11-13 has particular advantages when used with a distal tip of the configuration shown in Figures 21 and 22.

Figures 14 and 15 show a controller 790 of the invention which is an alternative to the controller 640 of the embodiment of the invention shown in Figures 11-13. The controller 790 forms a part of a steering mechanism having a distal end which may be identical to the embodiment of Figures 7 and 8, or may, as described below, be like the embodiment shown in Figures 21 and 22.

The controller 790 includes a housing 800 which receives a steering shaft 810, and also receives steering wires 820 and 830 through a wire retainer 835.

The housing 800 includes flanges 840 and 850 with coaxial bores (such as bore 860) therethrough, with bore 860 being formed through the flange 840 and another bore (not separately shown) being formed through flange 850. The bores have an axis which is substantially at

right angles to a longitudinal axis of the housing 800 and the steering shaft 810. The controller 790 includes a handle 870 having forwardly disposed flanges 880 and 890 which include transverse bores therethrough (not
5 separately shown) which are coaxial with the bores through the flanges 840 and 850. Extending through the bores in the flanges 840, 850, 880 and 890 is a shaft 900 (shown in Figure 15). The shaft includes an annular
10 bearing 910. As shown in Figure 15, the steering wires 820 and 830 are disposed on opposite sides of the bearing 910 and are affixed to the handle 870 by means of screws 920 and 930. A tightening knob 940 (shown in Figure 14) is coupled to the shaft 900, preferably by threading onto an end thereof, and is used to adjust friction in the
15 same manner as the knob 570 shown in Figure 9.

When the handle 870 is pulled to the left, as shown in dotted fashion in the lower portion of Figure 15, rearward tension is placed on the steering wire 830 and a forward force is exerted on the steering wire 820.
20 This causes the distal tip of the steering shaft to bend to the right, as shown in dotted fashion on the upper side of the steering shaft 320 in Figure 7. Conversely, when the handle 870 is pushed to the right with respect to the housing 840, as shown in dotted fashion in the
25 upper portion of Figure 15, rearward tension is placed on the steering wire 820 and a forward force is exerted on the steering wire 830, causing the distal tip of the steering shaft to bend to the left, as shown in dotted fashion on the lower side of the steering shaft 320 in
30 Figure 7. As with the embodiment of Figure 9, the knob 570 may be tightened such that the handle 870 will maintain whatever position it is placed in, or it may be loosened to allow much freer play to the handle 870.

Figures 16, 17A and 17B show another embodiment
35 of the controller of the invention. The controller 950 includes a housing 960 having an upper half 970 and a lower half 980. These halves are held together by screws

990. The housing 960 includes a bore 1000 in its distal end, for receiving a proximal end of a steering shaft 1010, in which steering wires 1020 and 1030 are positioned. The portion of the steering shaft 1010 and steering wires 1020 and 1030 to the left of Figure 16 may be identical to the distal portion of the steering shaft shown in Figures 7 and 8.

The housing 960 includes a cavity 1040 defined between the two halves 970 and 980, in which a disk 1050 is rotatably mounted, with its axis of rotation defined by a shaft 1060 disposed substantially at right angles to a longitudinal axis of the housing 960. The disk 1050 includes an upper half 1070 and a lower half 1080, into which are inserted dowels or pins 1090 and 1100. The pins 1090 and 1100 are received by coaxial bores (not separately shown) in the upper and lower halves 1070 and 1080, respectively. The pins 1090 and 1100 include heads or tips 1120 and 1130, which protrude above the upper half 1070 of the disk 1050. Corresponding arcuate slots 1140 and 1150 are provided in the lower surface of the upper half 970 of the housing 960, thus limiting the rotational travel of the disk 1050.

The steering wires 1020 and 1030 are clamped between the upper half 1070 and the lower half 1080. Attached to the upper end of the shaft 1060 is a knurled knob 1160, onto the lower end of which a nut 1170 is threaded, as shown in Figure 17B. The nut 1170 may include a press-nut portion 1110, which has a noncircular cross-section and is press-fit into the lower half 980 of the housing 960, as shown in Figure 17B. This allows the nut 1170 to be tightened without the use of a wrench.

The knob 1160 is used to adjust the friction imparted by the housing 960 to the disk 1050, in similar fashion to the knob 940 of the controller 790 shown in Figure 14.

A tab 1180 is formed on a side of the disk 1050, by protruding portions of the upper and lower halves 1070 and 1080. The tab 1180 forms a grip for the thumb of the operator. An additional tab (not separately shown) may be formed diametrically opposite the tab 1180.

The extreme proximal ends of the steering wires 1020 and 1030 are clamped in place around a bearing 1190 by means of a standard clamp 1200, which may include a conventional taper pin (like the taper pin 485 shown in Figure 10). The clamp 1200 is tightly received in a flared indentation 1210 formed in one or both of the halves 970 and 980 of the disk 960.

Thus, as the tab 1180 is pushed clockwise from the point of view of Figure 17A, rearward tension is placed on the steering wire 1030, and a forward force is exerted on the steering wire 1020. The distal tip of the steering shaft 1010 is thus turned to the right, as described previously with respect to the steering shaft 320 shown in Figure 7. Pushing on the tab 1180 counter-clockwise from the point of view of Figure 17A likewise turns the distal tip of the steering shaft 1010 to the left.

A tightening screw 1220 is preferably threaded into a bore 1230 in the housing 960, by which the tension on the steering wires 1020 and 1030 may be adjusted by screwing the tightening screw 1220 into or out of the bore 1230. This operates in the same fashion as the threaded bolt 510 shown in Figures 9 and 10.

Another embodiment of the invention is shown in Figures 18 and 19, depicting a controller 1240 which is an alternative to the controllers described above. The controller 1240 includes a housing 1250, including an upper half 1260 and a lower half 1270, which are held together by means of screws 1280. The housing receives a steering shaft 1285, in which are disposed steering wires 1290 and 1300. The distal portion of the steering shaft

1285 may be identical to the distal portion of the shaft 320 shown in Figure 7.

The steering wires 1290 and 1300 are attached to a rotator 1310, as shown in Figure 19. Any
5 conventional attachment method may be used, but in the embodiment shown the extreme proximal end of the steering wire 1290 passes through a tapered slot 1320 formed in the rotator 1310, and a wedge or taper pin 1330 is tightly fitted into the slot 1320, thus preventing the
10 steering wire 1290 from slipping out of the slot. Likewise, the steering wire 1300 is positioned in a slot 1340 and is maintained in position by a wedge or taper pin 1350. Tension on the steering wires 1290 and 1300 may be adjusted by means of a bolt 1360, just as with the
15 tightening screw 1220 shown in Figure 17A.

The rotator 1310 is rotatably mounted on a shaft 1370 which is substantially at right angles to a longitudinal axis of the housing 1250 and the longitudinal axis of the steering shaft 1285. A slot
20 1380 is formed between the upper and lower housing halves 1260 and 1270, as shown in Figure 18. Thus, the operator of the mechanism may turn the distal end of the steering shaft 1285 to the left or right by rotating the rotator 1310 counterclockwise or clockwise, respectively. Finger
25 holes 1390 and 1400 are formed by circular portions 1410 and 1420, which are in the preferred embodiment integral with the rotator 1310. This provides ease of operation of the controller 1240. Likewise, a finger hole or thumb hole 1430 is formed by a circular portion 1440 formed in
30 the housing 1250.

The rotator 1310 is operated in essentially the same fashion as the disk 1050 shown in Figure 16, but provides a different type of hand hold for the physician. A tightening knob 1450 is provided to adjust the friction
35 on the rotator 1310, just as with the knurled knob 1160 of the embodiment of Figure 16.

Figures 20-24 show an alternative embodiment of the invention, including a steering mechanism 1460 including steering wires 1470 and 1480, which terminate in distal tips 1490 and 1500, respectively. The steering mechanism 1460 includes a housing 1510, and shafts 1520 and 1530 which are transversely, rotatably mounted.

Carried on the upper end of shaft 1520 is a disk 1560 having an arcuate groove 1570 around its circumference. The disk 1560 is attached in a non-rotatable fashion to the shaft 1520. Mounted in the housing 1510 is a stop 1580, for limiting the rotational motion of the disks 1560 and hence of the shaft 1520, with the limit of rotation being determined by the arc length of the groove 1570. The shaft 1520 is rotated by turning the disk 1560.

Similarly, a disk 1590 is rigidly attached to the shaft 1530, and includes an arcuate groove 1600 around its perimeter. Another stop 1610 is mounted in the housing 1510, to limit the rotational motion of the disk 1590 and hence of the shaft 1530.

Knobs 1540 and 1550 are threaded onto the shafts 1520 and 1530, as shown in Figure 24, and provide rotational friction to the disks 1560 and 1590, respectively, in the same manner as the knob 570 shown in the embodiment of Figure 7.

As shown in Figure 23, the steering wire 1470 is attached to the shaft 1520 by passing the extreme proximal end thereof through a bore 1620 formed in the shaft 1520, and by fixing the proximal tip so that the steering wire 1470 cannot slip relative to the bore 1620. Similarly, steering wire 1480 is attached to the shaft 1530 through a bore 1630.

Affixation of each of the steering wires to the respective shafts may be accomplished by any standard means, such as by wrapping the steering wire around itself, or by welds, adhesives, clamps or the like. In a preferred embodiment, the steering wires 1470 and 1480

are attached to the shafts 1520 and 1530, respectively, by means of conventional taper pins 1632 and 1634, in a friction fit to prevent the wires 1470 and 1480 from accidentally coming loose.

5 In the embodiment of Figures 20-24, the steering wire 1470 is attached to the extreme distal tip of a lead spring 1640 carried within a steering shaft 1650. The lead spring is positioned within a slot of a ferrule 1660. The configuration of the lead spring 1640,
10 the ferrule 1660, and the attachment of the steering wire 1470 to the lead spring 1640 may be identical to the configuration of lead spring 350, ferrule 400, and steering wire 360 shown in Figure 8. The lead spring 1640 is held in place relative to the steering shaft 1650
15 by means of an adhesive 1670. The adhesive 1670 may include an electrically conductive material, if the steering shaft 1650 is to be utilized in an embodiment wherein an electrode is desired at the tip of the steering shaft.

20 In this embodiment, the steering wire 1480 is attached at its distal tip to the lead spring 1640 at a point somewhat removed from the distal tip thereof, as shown in Figures 21 and 22. With this configuration, rotation of the shaft 1520 so as to place tension on the
25 steering wire 1470 will cause the extreme distal tip of the steering shaft 1650 to turn to the left, while placing tension on the steering wire 1480 (by rotating the shaft 1530) will cause the steering shaft 1650 to turn to the right at the point of attachment of the
30 steering wire 1480 to the lead spring 1640. Such a configuration is shown in Figure 21.

 This embodiment has several advantages. For instance, tortuous paths may be negotiated by the tip of the steering shaft 1650 by operation of the knobs 1560
35 and 1590 while the physician views on a fluoroscope. Also, if the catheter (such as catheter 40 shown in Figure 35) is to be positioned in a vessel which is

complicated in shape, the configuration of Figure 21, or variations thereon, may be the only way to position the distal tip of the steering shaft 1650 without placing too much stress on internal body structures. Another
5 advantage is that the extreme distal tip of the steering shaft 1650 may be placed in position within the patient, and tension may then be taken off of the steering wire 1470, so that the distal tip of the steering shaft 1650 is free to flex, limited only by the flexibility of the
10 lead spring 1640. However, at the same time, a bend may be retained in the portion of the steering shaft 1650 adjacent the attachment of the steering wire 1480 to the lead spring 1640, which is of particular importance where the catheter must make a turn very near the final
15 emplacement point of the distal tip thereof, such as in the human heart.

Because the knobs 1560 and 1590 are operable independently of one another, the embodiment of Figure 20 may take the hook-shaped configuration shown in Figures
20 20 and 21. However, the offset attachment of the steering wires 1470 and 1480 shown in Figure 21 may also be used with other embodiments of the invention herein, indeed wherever two steering wires are used, such as in the embodiments of Figures 7, 11, 13, 16, and 18. In the
25 embodiments where the steering wires are not independently operable, the hook-shaped configuration of Figure 21 is not achieved. However, flexibility in the guiding of the distal tip of the steering shaft is in each case provided, by allowing bends in the distal tip
30 of the steering shaft to be made at different points along its length, such as at its extreme distal tip and somewhat further back thereof. This provides an extra measure of flexibility over the design of Figure 1.

Shapes other than the hook shape of Figure 21
35 may be achieved with different locations of attachment of the steering wires to the lead spring. Also, more than two steering wires may be used, if desired, with the

vari us embodiments described herein. For instance, it may be desirable to have two offset steering wires attached to one side of the lead spring and one steering wire attached to the other side of the lead spring, to accommodate a particular configuration of emplacement. Alternatively, it may be useful for particular applications to attach steering wires at different angles circumferentially around a lead spring (which may be oval or polygonal in cross section). Other variations on the number, attachment and positioning of the steering wires may be made, and the shapes of the steering wires and the lead spring may be adapted accordingly.

Further flexibility may be accomplished by the present invention utilizing the configurations of Figures 33 and 34. In this embodiment, a steering shaft 1680 includes a distal tip 1690, having regions 1700 and 1710 of enlarged diameter. A lead spring 1720 is positioned within the distal tip 1690, and has its proximal end mounted in a ferrule 1730. A steering wire 1740 is attached at its extreme distal tip to the lead spring 1720, such as at weld 1750. The configuration of the lead spring 1720, ferrule 1730, and steering wire 1740 may be essentially identical to the embodiment of Figure 2.

When tension is placed on the steering wire 1730, it will be seen from Figure 34 that the distal end 1690 of the steering shaft 1680 takes sharp bends in two places, namely in the regions 1700 and 1710. This allows the physician greater flexibility in maneuvering around particular obstructions and negotiating difficult pathways through a vessel in the patient's body. Both this embodiment and the embodiment of Figures 20-24 may be carefully constructed such that the distance between bends and the resultant radii of curvature are adapted for a particular medical or other applications. For instance, the embodiments of Figures 20-24 or 33-34 may be custom designed for emplacement within the left v ntricle of the heart, given the known shape of the

heart. Other adaptations are easily accomplished with these designs.

5

10

15

20

25

30

35

What is claimed is:

1. A steering mechanism, including:
 - a steering shaft having a proximal end and a
5 distal end and a lumen therethrough;
 - a coiled spring mounted in said steering shaft;
 - a lead spring positioned within said distal end
and fixed in place relative to said coiled spring;
 - a first steering wire extending through said
10 lumen, having a first end attached to said lead spring at
a first location and having a second end exiting said
proximal end;
 - a second steering wire extending through said
lumen, having a third end attached to said lead spring at
15 a second location and having a fourth end exiting said
proximal end;
 - a controller positioned at said proximal end
and attached to said second and fourth ends, for placing
tension on at least one of said first steering wire and
20 said second steering wire, for causing said distal end to
bend toward the tensed steering wire.

2. The steering mechanism of claim 1, wherein
said controller includes:
 - 25 a housing connected to said steering shaft;
 - a shafted rotatably carried by said housing and
having an axis mounted nonparallel to a longitudinal axis
of said housing;
 - means for attaching said second and fourth ends
30 to said shaft, such that rotation of said shaft in a
first direction places tension on said first steering
wire and rotation of said shaft in a second direction
places tension on said second steering wire; and
 - means attached to said shaft for rotating said
35 shaft.

3. The steering mechanism of claim 2, wherein said rotating means includes a knob protruding from said housing for manual rotation of said shaft.

5 4. The steering mechanism of claim 2, wherein said rotating means includes a handle which is coupled to said shaft and which is rotatable relative to said housing for exerting tension on said first and second steering wires.

10 5. The steering mechanism of claim 2, including means for adjusting rotational friction on said shaft.

15 6. The steering mechanism of claim 1, wherein said first and second attachment locations for said steering wires are longitudinally offset from one another with respect to said lead spring, for causing a bend at said first location when said first steering wire is
20 tensed, and for causing a bend at said second location when said second steering wire is tensed.

 7. The steering mechanism of claim 1, wherein said first and second attachment locations for said
25 steering wires are on opposite sides of said lead spring from one another, for causing a bend in a first direction when said first steering wire is tensed, and for causing a bend in a second direction when said second steering wire is tensed.

30 8. The steering mechanism of claim 1, wherein said housing includes a transverse opening, and said controller includes:

 a first wedge which is tapered from a narrow
35 end to a broad end and is slidably mounted in said transverse opening, said first wedge having a first slot extending from said narrow end to said broad end and

receiving said second end of said first steering wire,
with said first steering wire being slidable within said
first slot;

5 first means for maintaining said second end in
said first slot;

a second wedge which is tapered from a narrow
end to a broad end and is slidably mounted in said
transverse opening, said second wedge having a second
slot extending from said narrow end to said broad end and
10 receiving said fourth end of said second steering wire,
with said second steering wire being slidable within said
first slot;

second means for maintaining said fourth end in
said second slot;

15 with said first and second wedges being mounted
in said opening such that their respective tapers run in
opposite directions, such that sliding said first wedge
with respect to said housing such that its broad portion
moves into said opening exerts force on said first
20 maintaining means, thereby exerting tension on said first
steering wire, and such that sliding said second wedge
with respect to said housing such that its broad portion
moves into said opening exerts force on said second
maintaining means, thereby exerting tension on said
25 second steering wire, whereby said first and second
steering wires may be independently tensed.

9. The steering mechanism of claim 1, wherein
said controller includes:

30 a housing connected to said steering shaft;
a first shaft rotatably mounted in said
housing, with said second end of said first steering wire
being attached to said first shaft;

a second shaft rotatably mounted in said hous-
35 ing, with said fourth end of said second steering wire
being attached to said second shaft;

first means attached to said first shaft for rotating said first shaft, and second means attached to said second shaft for rotating said second shaft, for placing tension on said first and second steering wires independently of one another.

10. The steering mechanism of claim 9, wherein said first and second attachment locations for said steering wires are on opposite sides of said lead spring from one another and are longitudinally offset, for causing a bend at said first location in a first direction when said first steering wire is tensed, and for causing a bend at said second location in a second direction when said second steering wire is tensed.

11. The steering mechanism of claim 1, wherein said steering shaft includes a section of enlarged diameter for bending said steering shaft to a greater degree near said section than in a region removed from said section.

12. A steering mechanism for a catheter having a proximal end and a distal end and a lumen, including:
a lead spring disposed in the distal end within said lumen and having a distal end and a proximal end, and further having a first side and a second side;

means for fixing said lead spring relative to said distal end to prevent relative longitudinal movement but to allow lateral flexing of said lead spring and the distal end;

a first steering wire having a distal tip affixed to said lead spring near said lead spring distal tip on said first side;

first means, attached to the proximal end of the catheter, for exerting tension on said first steering wire;

a second steering wire having a distal tip affixed to said lead spring near said lead spring distal tip on said second side; and

5 second means, attached to the proximal end of the catheter, for exerting tension on said second steering wire.

13. The steering mechanism of claim 12, wherein said distal tips of said first and second
10 steering wires are attached to said lead spring at locations which are offset with respect to one another.

14. The steering mechanism of claim 12, wherein:

15 said steering mechanism further includes a steering shaft having a central lumen and positioned within said lumen of said catheter, and further includes a coiled spring positioned within said steering shaft lumen;

20 said fixing means includes a ferrule mounted at a distal end of said coiled spring, said ferrule including a longitudinal bore and a transverse slot; said lead spring is mounted within said slot; said first and second steering wires pass
25 through said longitudinal bore; and

each of said steering shaft lumen and said bore has an inner diameter which is less than a combined outer diameter of said lead spring and said first and second steering wires.

30

15. A steering mechanism, including:

a steering shaft having a proximal end and a distal end and a lumen therethrough;

a coiled spring mounted in said steering shaft;

35 a ferrule positioned at a distal end of said coiled spring adjacent said distal end of said steering shaft, and having a central bore and a transverse slot;

a lead spring positioned within said transverse slot and fixed in place relative to said coiled spring;

5 a steering wire extending through said lumen and said central bore of said ferrule, having a first end attached to said lead spring at a first location and having a second end exiting said proximal end of said steering shaft, wherein said steering shaft and ferrule have inner diameters which are larger than a combined outer diameter of said lead spring and said steering
10 wire;

a controller positioned at said proximal end and attached to said second end, for placing tension on said first steering wire, for causing said distal end to bend toward the tensed steering wire.

15

16. The steering mechanism of claim 15, wherein said controller includes:

a housing connected to said steering shaft;
a shafted rotatably carried by said housing and
20 having an axis mounted nonparallel to a longitudinal axis of said housing;

means for attaching said second end to said shaft, such that rotation of said shaft places tension on said steering wire; and

25

means attached to said shaft for rotating said shaft.

30

35

1/7

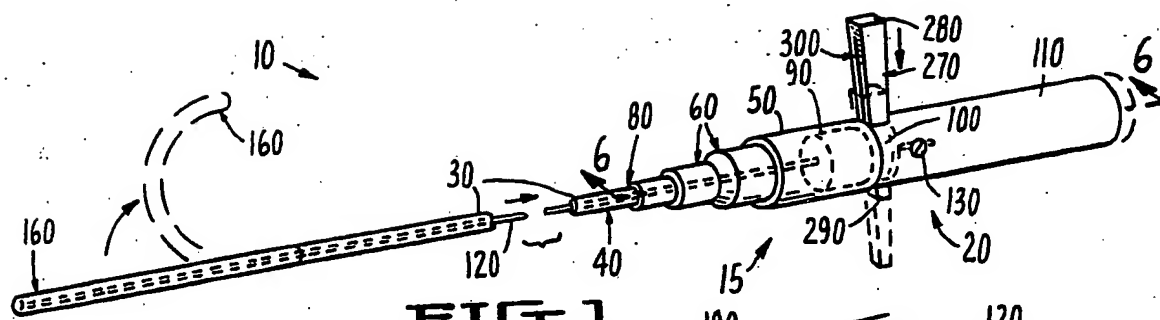


FIG. 1

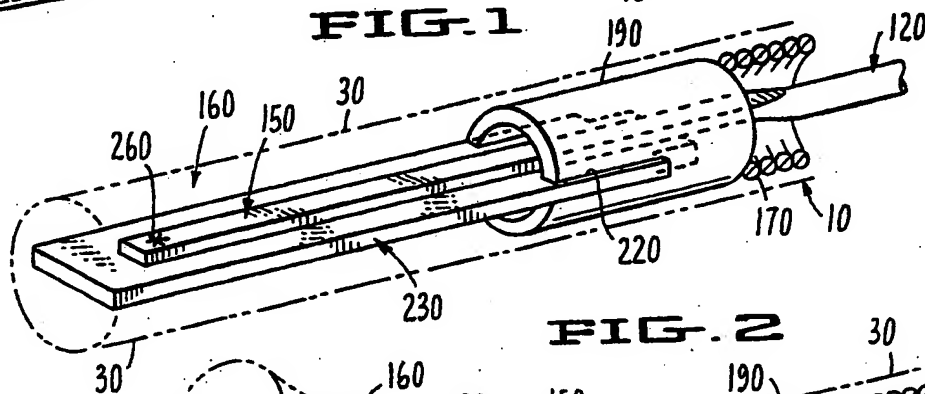


FIG. 2

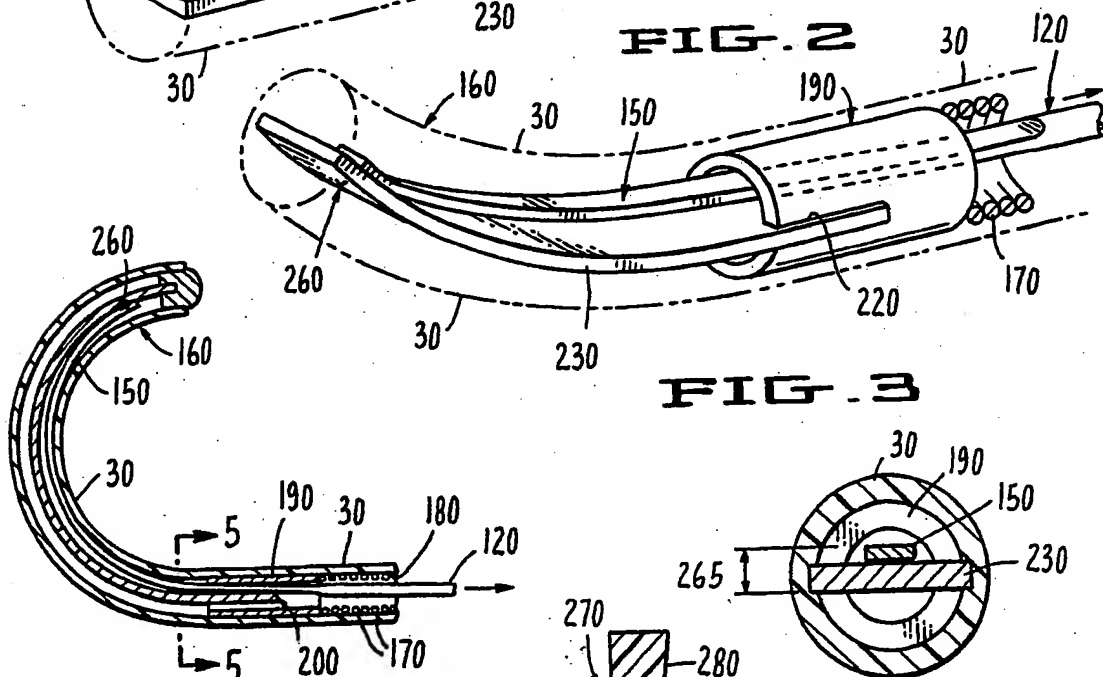


FIG. 3

FIG. 4

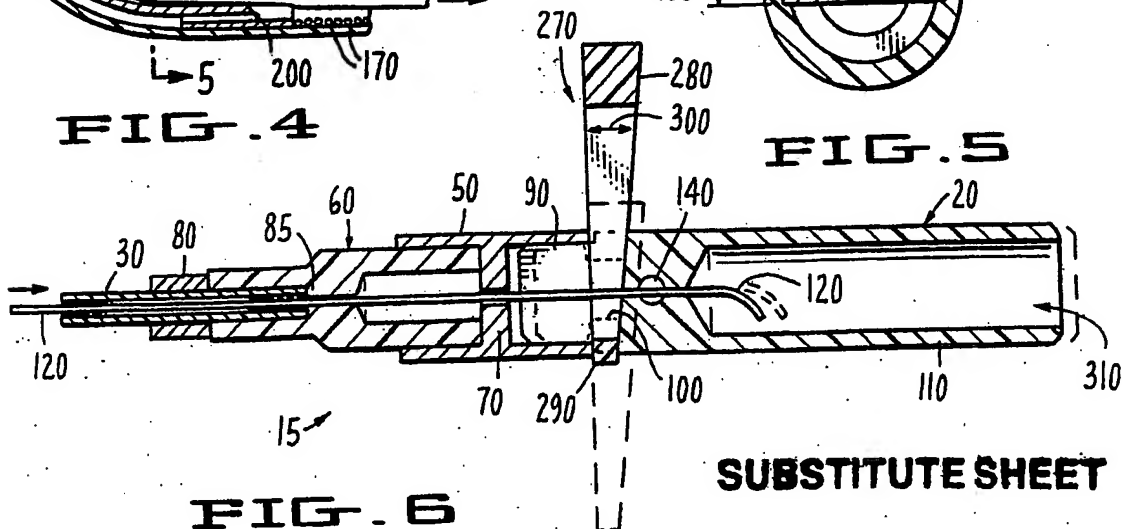


FIG. 5

FIG. 6

SUBSTITUTE SHEET

2 / 7

FIG. 7

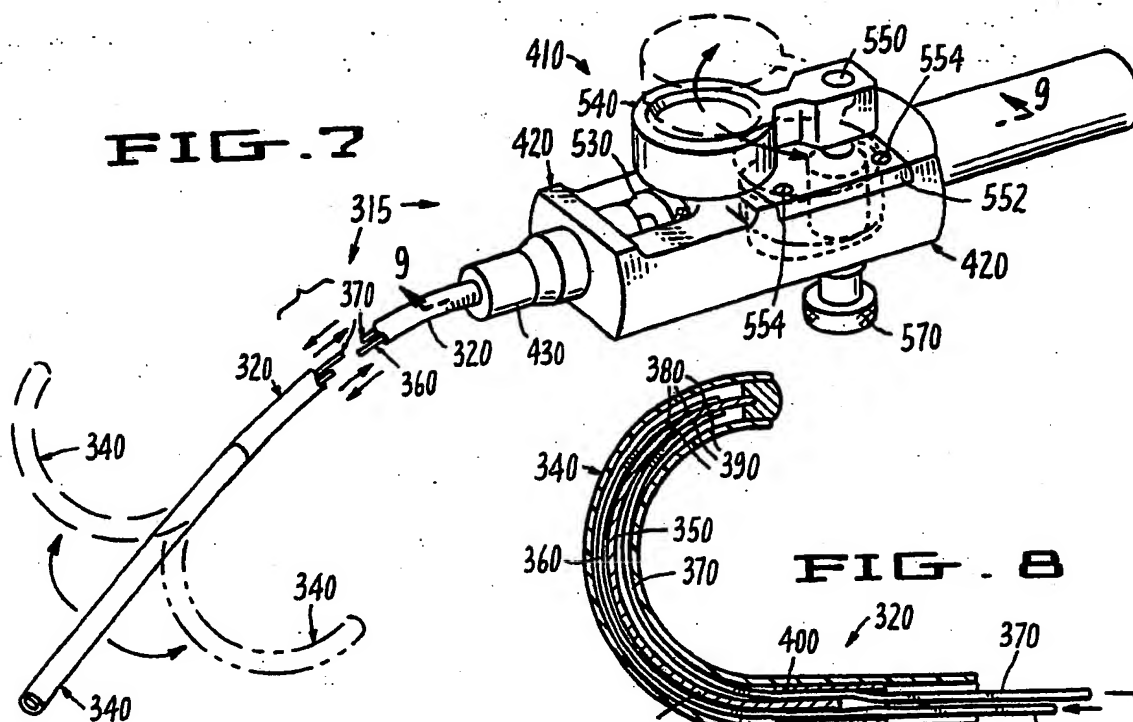


FIG. 8

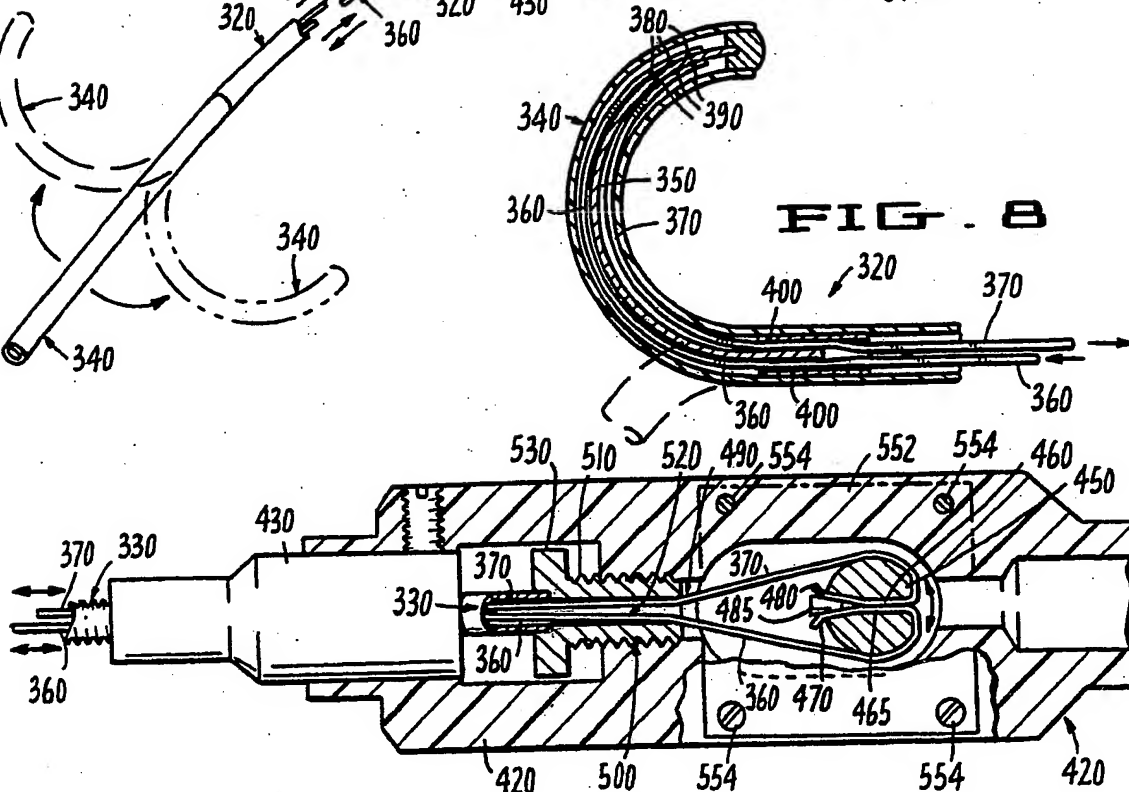


FIG. 10

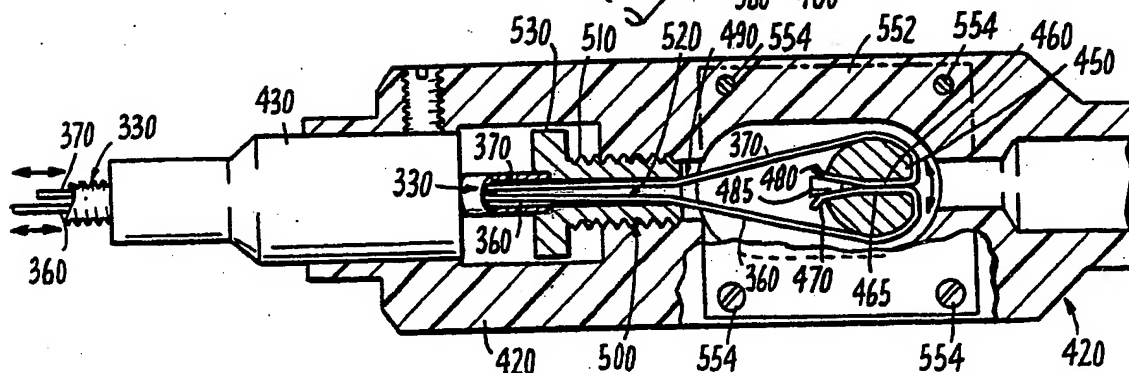
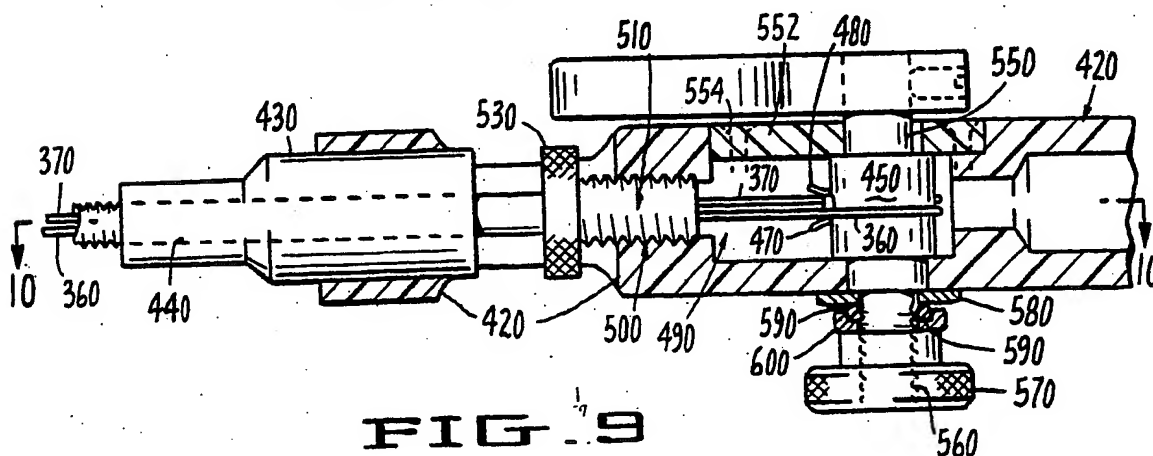


FIG. 9



3 / 7

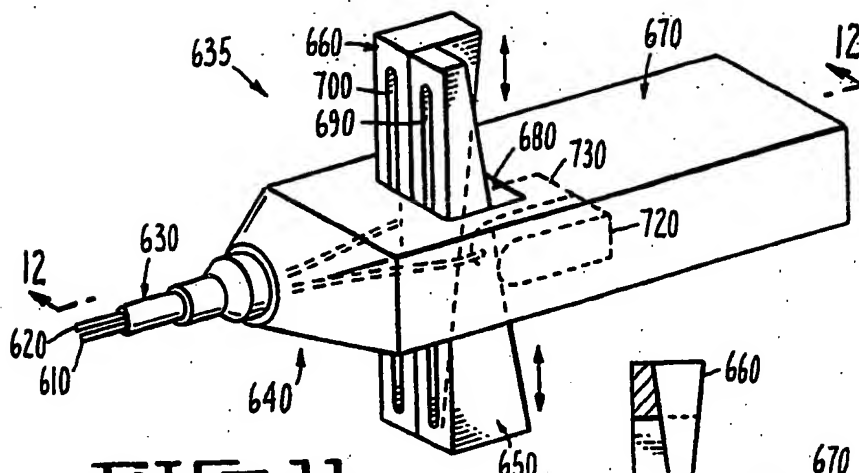


FIG. 11

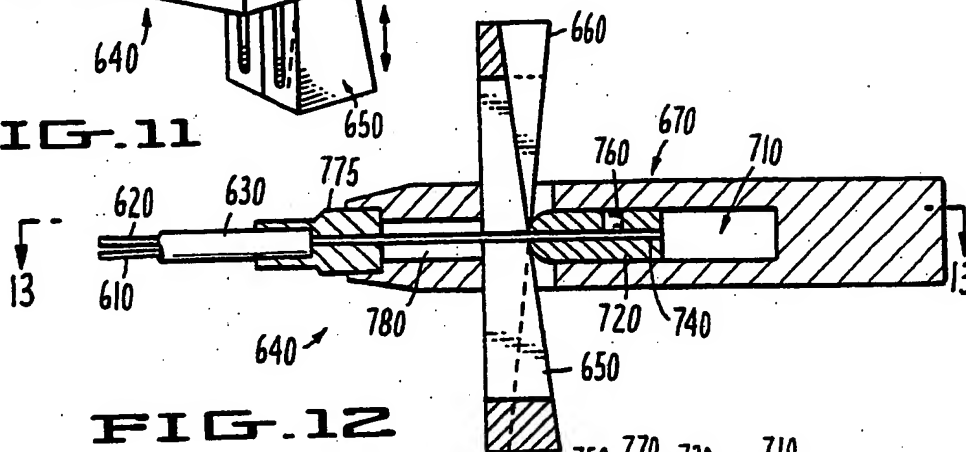


FIG. 12

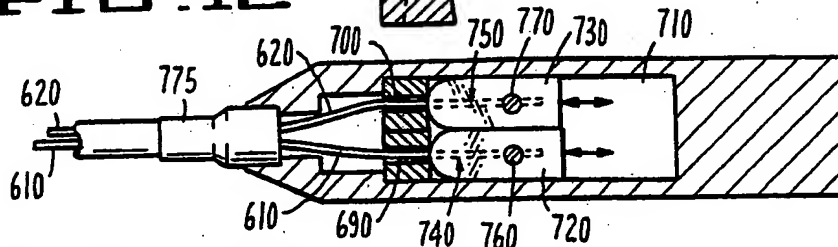


FIG. 13

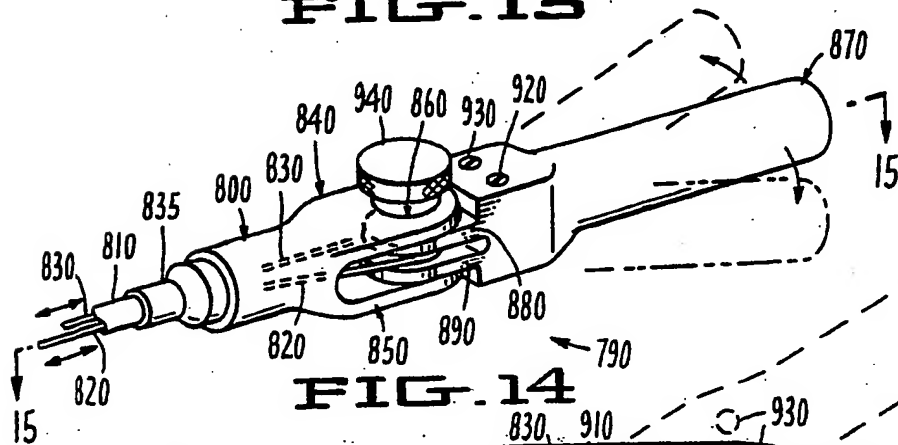


FIG. 14

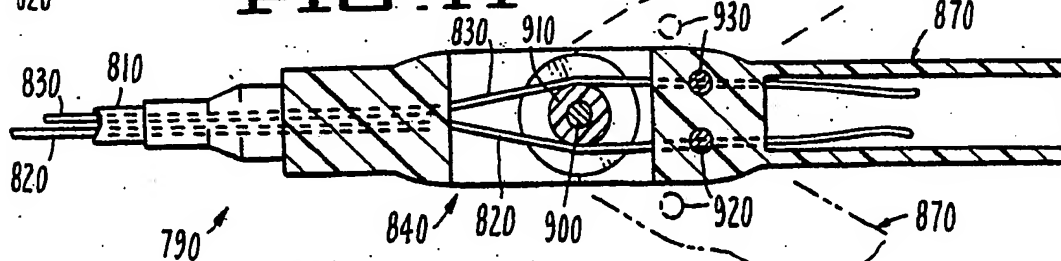
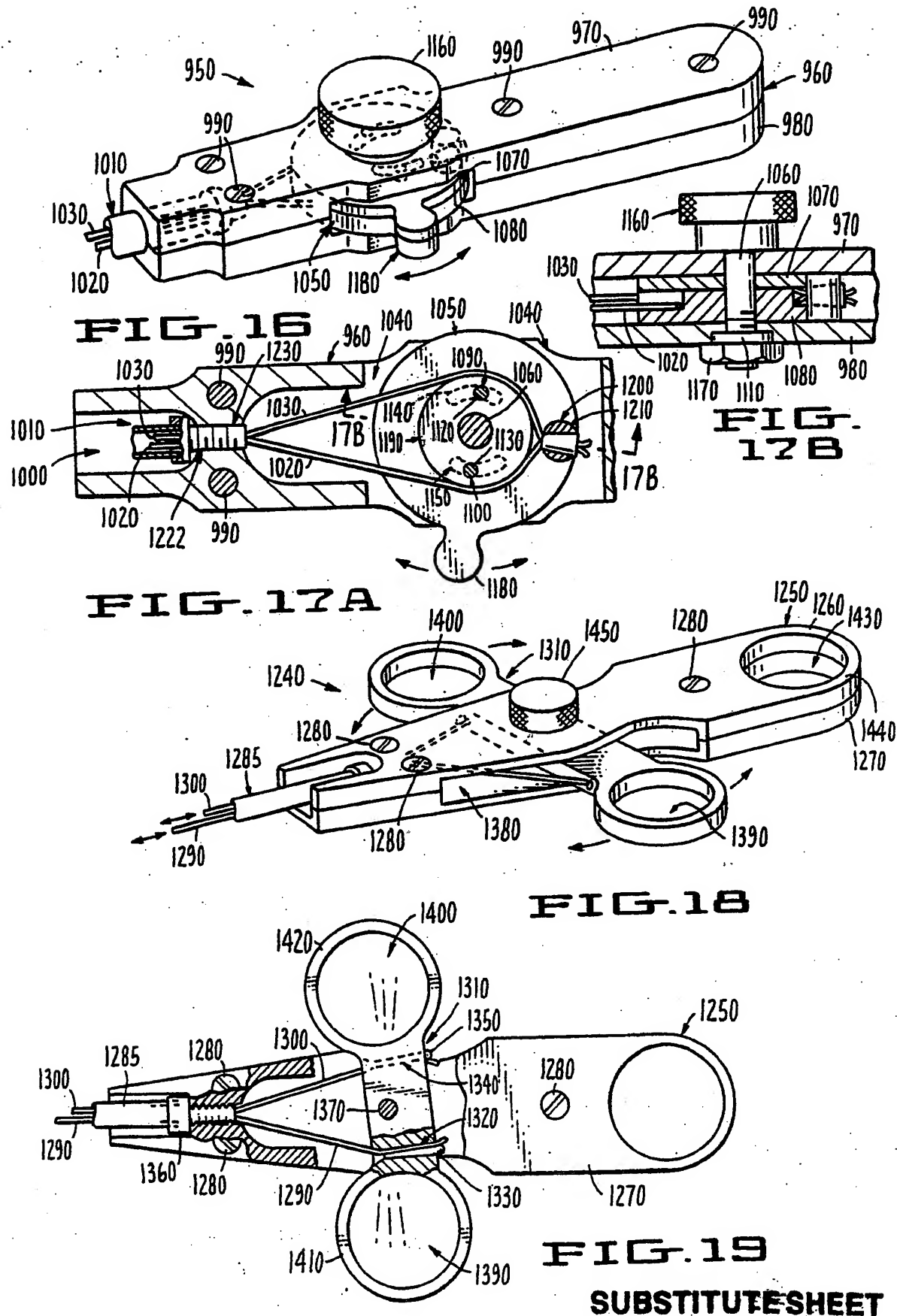


FIG. 15

4 / 7



SUBSTITUTE SHEET

5/7

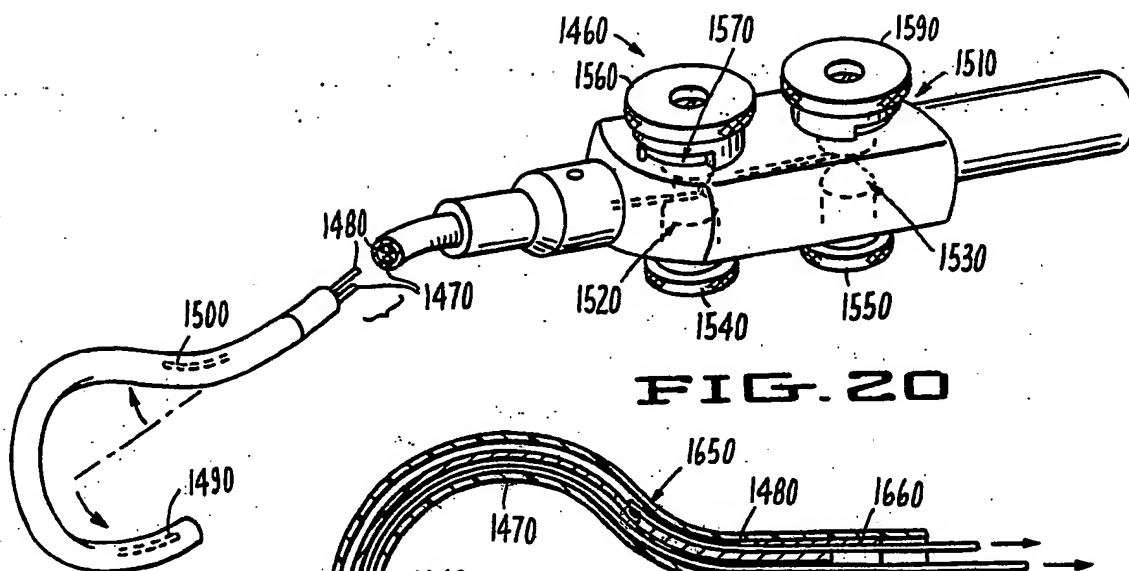


FIG. 20

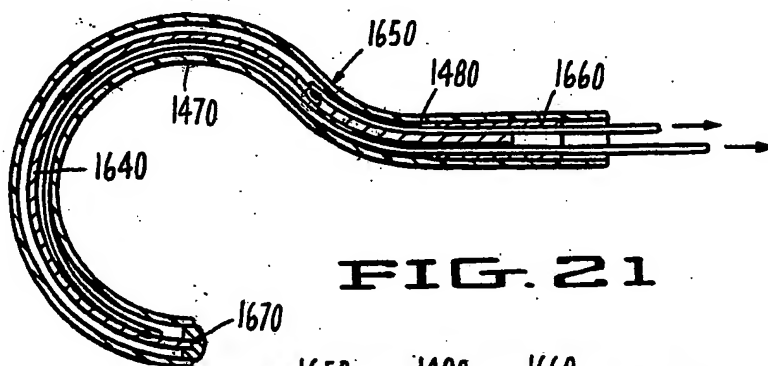


FIG. 21

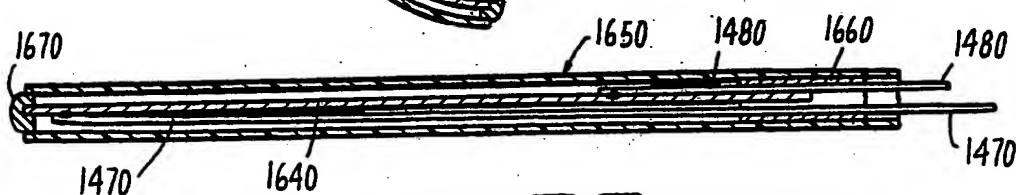


FIG. 22

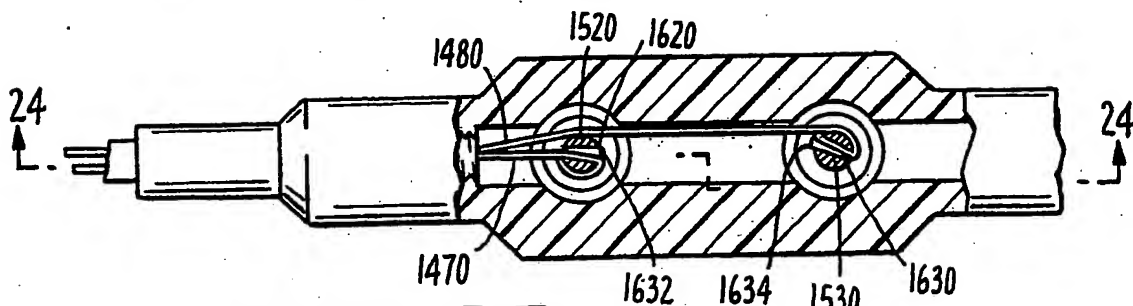


FIG. 23

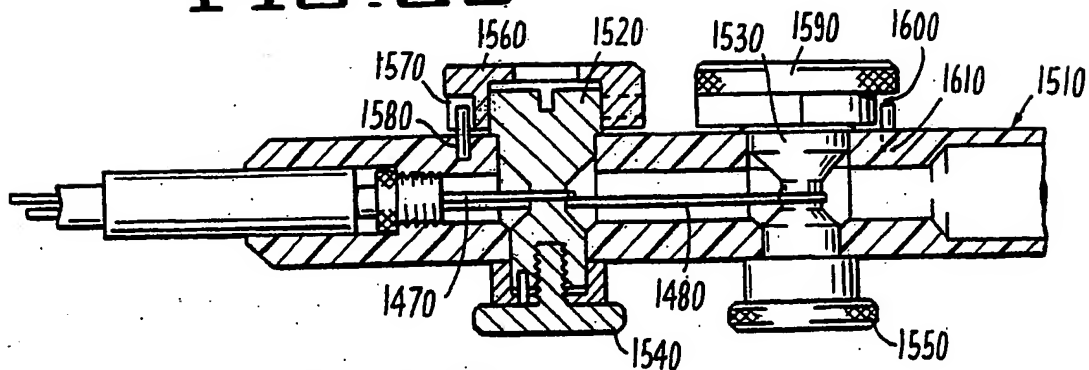
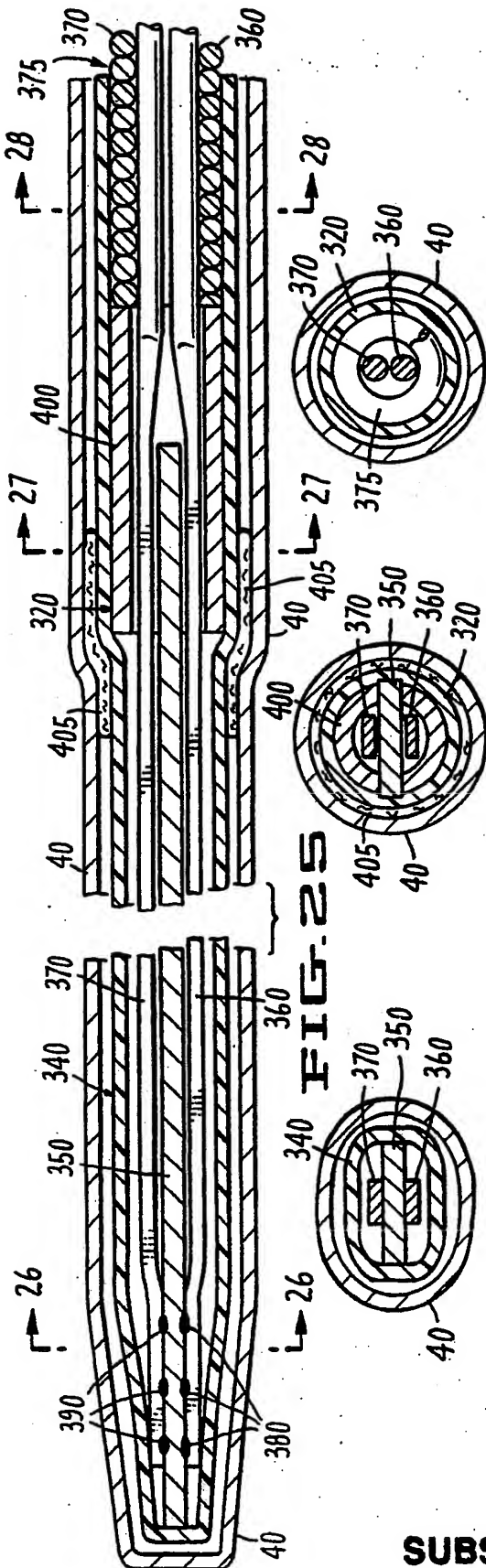


FIG. 24



92515

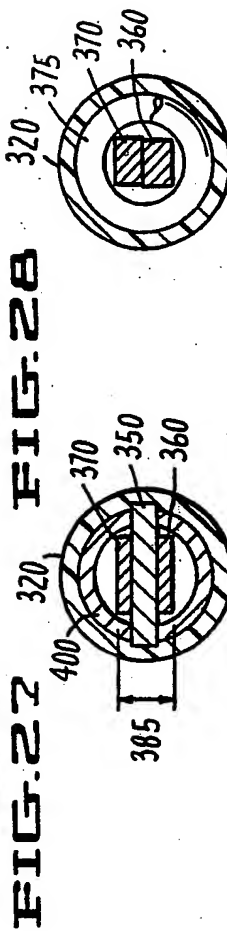
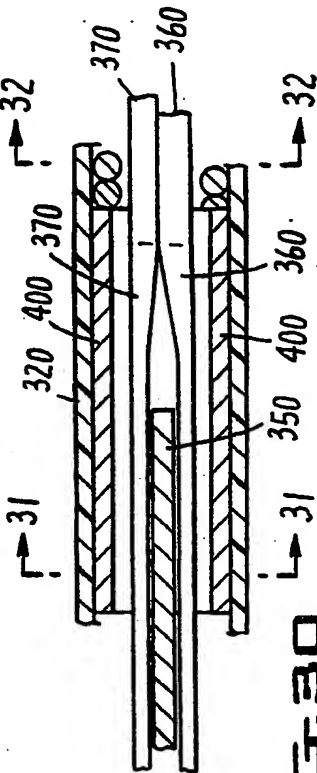
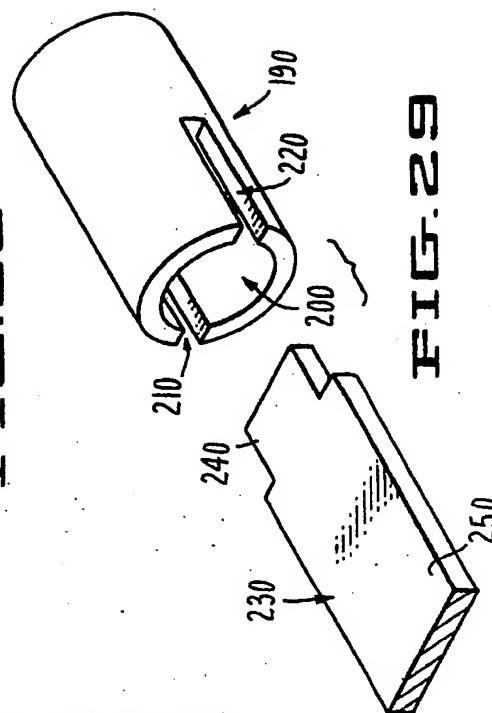


FIG. 31



DESI



ENTR

7/7

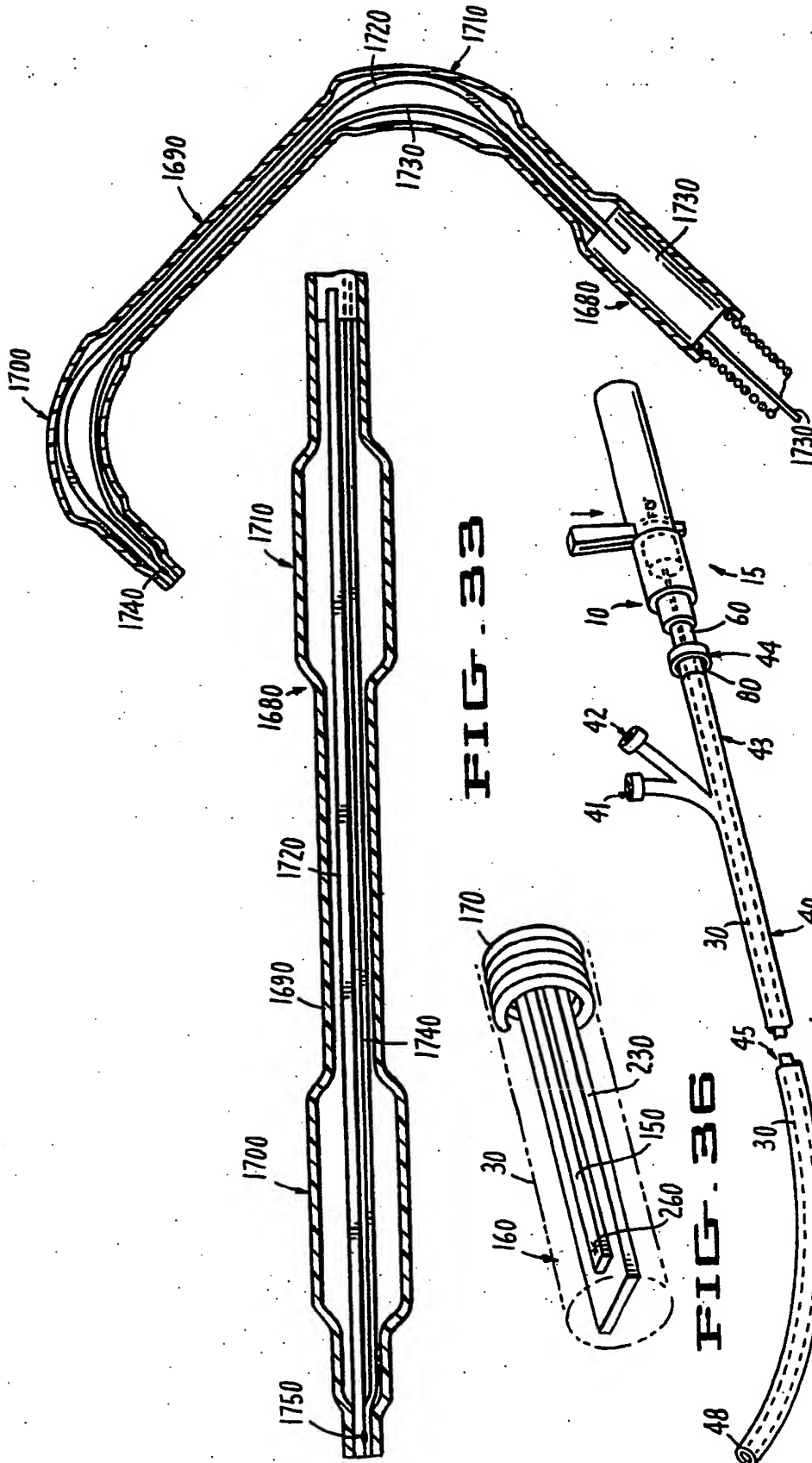


FIG. 33

FIG. 34

FIG. 35

FIG. 36

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/00662

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC (5): A61M 37/00;		
U.S. CL: 604/95		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
U.S.	604/95, 164-167 128/772, 656-658	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
<u>Y</u> <u>A</u>	<u>Surgery</u> , Vol.27, No.6, June 1950, pp 817-821, [SMITH ET AL.] " <u>preliminary report on a new method of intestinal intubation with the aid of a flexible stylet with controllable tip</u> ".	1-4, 7 6, 8-10, 12-16
<u>Y,P</u> <u>A,P</u>	US, A, 4,921,482 [HAMMERSLAG ET AL] 01 May 1990 (See Figs 1-3)	1-4, 7 6, 8-10, 12-16
<u>Y,P</u> <u>A,P</u>	US, A, 4,944,727 [McCOY] 31 July 1990 (See Fig 12)	1-4, 7 6, 8-10, 12-16
A	US, A, 3,470,876 [BARCHILON] 07 October 1969 (See Figs 4,8)	1-16
A	US, A, 3,625,200 [MULLER] 07 December 1971 (See Fig. 1).	1-16
A	US, A, 4,586,923 [GOULD ET AL] 06 May 1986 (See Fig. 3).	1-16
A	US, A, 4,719,924 [CRITTENDEN ET AL] 19 January 1988 (See Figs. 3,5,6).	1-16
<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
01 MAY 1991	13 JUN 1991	
International Searching Authority	Signature of Authorized Officer	
ISA/US	ADAM J. CERMAK	